

4400 Health Systems Protection

4404 Free Standing Emergency Centers

1.0 Definitions

"Free Standing Emergency Center" means a facility physically separate from a hospital, which uses in its title or in its advertising, the words "emergency", "urgent care", or parts of those words or other language or symbols which imply or indicate to the public that immediate medical treatment is available to individuals suffering from a life-threatening medical condition. The facility rendering such care is capable of treating all medical emergencies that have life-threatening potential.

2.0 License Requirement

- 2.1 No person shall establish, conduct or maintain in this State any Free Standing Emergency Center without first obtaining a license from the Division of Public Health.
- 2.2 Existing Institutions
 - 2.2.1 No person shall continue to operate an existing Free Standing Emergency Center unless such facility is approved and regularly licensed by the State Board of Health as provided in this chapter.
- 2.3 Trailblazing Signs
 - 2.3.1 No Free Standing Emergency Center, treatment facility, office or station shall be authorized to exhibit any Trailblazing signs, symbols or directional signs by the State Highway Department unless such facility has been duly licensed under the provisions of this chapter.
- 2.4 Transfer Agreement
 - 2.4.1 The Free Standing Emergency Center shall have a written transfer agreement with one or more hospitals which provides the basis for effective working arrangements in which inpatient hospital care or other hospital services are available promptly to the facility's patients when needed.

3.0 Application on for License and Ownership

- 3.1 Application for license to establish, maintain or operate a Free Standing Emergency Center shall be made to the Division of Public Health stating the location thereof, the name of the person in charge and all other information necessary to determine the qualifications of the applicant.
- 3.2 Ownership
 - 3.2.1 The ownership and control of the facility and the property on which the Free Standing Emergency Center is located shall be disclosed to the Division of Public Health. Proof of this ownership must be produced upon request of authorized persons within three (3) working days. Any change in ownership shall be reported to Office of Health Facilities Licensing and Certification in writing prior to the change.

4.0 Inspections

- 4.1 Every Free Standing Emergency Center for which a license has been issued under this chapter shall be periodically inspected by a representative of the Division of Public Health.

5.0 Issuance of Licenses

- 5.1 Licenses shall be issued in the following categories:
 - 5.1.1 Annual License. An annual license (12 months) may be renewed yearly if the holder is in full compliance with the provisions of this chapter and the rules and regulations of the Division of Public Health.

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- 5.1.2 Provisional License. A provisional license shall be granted for a term of three (3) months only and shall be granted only to a Free Standing Emergency Center which, although not in full compliance, is nevertheless demonstrating evidence of improvement.

6.0 Suspension or Revocation of License

- 6.1 The Division of Public Health may suspend or revoke a license issued under this chapter on any of the following grounds:
- 6.1.1 Violation of any of the provisions of this chapter or the rules and regulations issued pursuant thereto.
 - 6.1.2 Permitting, aiding or abetting the commission of any illegal act in the facility.
 - 6.1.3 Conducts or practices detrimental to the welfare of the patient.
 - 6.1.4 Before any license issued under this chapter is suspended or revoked, one (1) month notice shall be given in writing to the holder of the license, during which time he may appeal for a hearing before the Division of Public Health.
- 6.2 Emergency Suspension
- 6.2.1 The Division of Public Health may suspend a license without a hearing if it finds that there is an immediate danger to the public health and safety which warrants this action. A hearing on the suspension should be scheduled before the Board no more than 30 days after the licensee is notified of the suspension. The suspension shall continue in effect until the conclusion of the proceedings, including judicial review thereof unless sooner withdrawn by the Division or dissolved by a court of competent jurisdiction.
- 6.3 Renewal of License After Suspension on or Revocation on
- 6.3.1 If and when the conditions upon which the suspension or revocation of a license are based have been corrected and after a proper inspection has been made, a new license may be granted.

7.0 Regulations

- 7.1 The Division of Public Health may adopt, amend or repeal regulations governing the operation of Free Standing Emergency Centers and shall establish reasonable standards of equipment, capacity, sanitation and any other conditions which might influence the health or welfare of patients of such facilities.

8.0 Penalties

- 8.1 Whoever operates a Free Standing Emergency Center in violation of these regulations shall be fined not less than \$100.00 nor more than \$1,000.00 for each offense. Every day such violation continues shall constitute a separate and distinct offense.

9.0 Licensing Requirements and Procedures

- 9.1 When a facility is classified under this law and/or regulation and plans to construct, extensively remodel or convert any building, two (2) copies of properly prepared plans and specifications for the entire institution are to be submitted to the Division of Public Health. An approval, in writing, is to be obtained before such work is begun. After the work is completed, in accordance with the plans and specifications, a new license to operate will be issued.
- 9.2 Separate licenses are required for facilities maintained in separate locations, even though operated under the same management. A separate license is not required for separate buildings maintained by the same management on the same grounds. A license is not transferable from person to person nor from one location to another.
- 9.2.1 In the event of the sale of a "Free Standing Emergency Center", the prospective buyer shall be informed of the waivers which were officially granted the previous owner. The Division of Public Health may grant the new owner the same waivers which had been granted to the former owner, with the condition that a plan for correcting all deficiencies within a reasonable time may be required to be submitted to and be acceptable to the Office Of Health Facilities Licensing And Certification prior to issuance of a license.

- 9.3 The license shall be conspicuously posted.
- 9.4 All applications for renewal of licenses shall be filed with the Division of Public Health at least thirty (30) days prior to expiration.
- 9.5 All required records necessary to determine compliance with this regulation shall be open to inspection by the authorized representatives of the Division of Public Health.
- 9.6 The terms emergency, urgent care or parts of those terms or any other language or symbols which imply or indicate to the public that immediate medical treatment is available to individuals suffering from a life threatening medical condition shall not be used as part of the name of any facility in this State, unless the facility has been licensed by the Division of Public Health.
- 9.7 No rules shall be adopted by the licensee or administrator of any facility which are in conflict with these regulations.
- 9.8 The Division of Public Health shall be notified, in writing within thirty (30) days of any changes in the administrator or director of the facility.
- 9.9 The "Free Standing Emergency Center" must establish written policies regarding the rights and responsibilities of patients, and these policies and procedures are to be made available to patients, guardians, next of kin or sponsoring agency(ies).
- 9.10 Each facility shall make available upon request to all patients or their sponsors, a complete statement enumerating all charges for service, materials and equipment which were furnished to the patient.
- 9.11 Each facility shall conspicuously post the prepayment policy. In the event of third-party payment denial, a policy statement must be developed in writing and available upon request as to the responsibility for payment.
- 9.12 A facility licensed under the provisions of this regulation as a "Free Standing Emergency Center", shall not refuse to render a needed, medically appropriate emergency service to any person because of that person's inability to pay for the service.
- 9.13 Each facility shall coordinate with the office of Emergency Medical Services in regards to transfer agreements, communications requirements and disaster planning and preparedness.
- 9.14 The Office of Emergency Medical Services and the Office of Narcotics and Dangerous Drugs shall be notified by the Office of Health Facilities Licensing and Certification of any proposal of licensing of Free Standing Emergency Centers.

10.0 Personnel

10.1 Clinical Staff

- 10.1.1 The Free Standing Emergency Center shall have an organized clinical staff under the immediate and personal supervision of licensed physicians and nurses to provide emergency health care services 24 hours per day.
- 10.1.2 At least one Licensed Nurse and Physician must be present in the facility at all times.

10.2 Clinical Staff Requirements

- 10.2.1 Each staff Physician shall be licensed to practice medicine in the State of Delaware and provide proof of licensure number.
- 10.2.2 All staff Physicians must maintain current certification in Advanced Cardiac Life Support. (A Physician currently certified by American Board of Emergency Medicine needs no other certifications for delivery of emergency care.)
- 10.2.3 Each staff nurse shall be licensed as a Professional Nurse in the State of Delaware and provide proof of license number.
- 10.2.4 All members of the nursing team must maintain current certification in CPR.
- 10.2.5 At least one member of the nursing team on duty must be currently certified in Advanced Cardiac Life Support.

11.0 Medical Records

- 11.1 A medical record must be maintained on every patient seeking care in the Free Standing Emergency Center.

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- 11.2 The Free Standing Emergency Center shall provide sufficient space and equipment for the processing and safe storage of records.
- 11.3 Medical records shall be protected from loss, damage and unauthorized use.
- 11.4 Medical records of individuals eighteen years or older shall be preserved as original records or microfilm for no less than five (5) years after the most recent patient care usage, after which time records may be destroyed at the discretion of the facility. Medical records of minors (under the age of 18) shall be preserved for the period of minority plus five (5) years.
- 11.5 The Facility shall establish procedures for destruction of Medical Records.
- 11.6 Each time a patient visits the Free Standing Emergency Center the medical record shall contain sufficient accurate information. This information must include, but is not limited to:
 - 11.6.1 Complete patient identification and a unique identification number. When identification is not obtainable, the reason is entered in the medical record.
 - 11.6.2 Date, time and means of arrival and discharge.
 - 11.6.3 Pertinent history of the illness or injury and physical findings including the patient's vital signs.
 - 11.6.4 A complete description of emergency care given to the patient prior to arrival.
 - 11.6.5 A complete detailed description of treatment and procedures performed in the Free Standing Emergency Center.
 - 11.6.6 Clinical observations including the results of treatment.
 - 11.6.7 Reports of procedures, tests and results.
 - 11.6.8 Diagnostic impression.
 - 11.6.9 All medication and treatment orders signed by the prescribing physician.
 - 11.6.10 Conclusion at the termination of evaluation and/or treatment, including final disposition, the patient's condition on discharge or transfer and a copy of any instructions given to the patient and/or family for follow-up care.
- 11.7 All orders for diagnostic procedures, treatments and medications shall be signed by the physician submitting them and entered in the medical record in ink or type. Authentication may be by written signature, identifiable initials or computer key. The use of rubber stamp signatures is acceptable under the following strict conditions:
 - 11.7.1 The physician whose signature the rubber stamp represents is the only one who has possession of the stamp and is the only one who uses it, and it may not be used for controlled substances.
 - 11.7.2 The physician places in the administrative office of the facility, a signed statement to the effect that he/she is the only one who has the stamp and is the only one who will use it.
- 11.8 Standard nursing practice and procedure shall be followed in the recording of medications and treatments including treatment notes. Nursing notes shall include notation of the instructions given patients at the time of discharge. All recordings shall be in ink and properly signed including name and identifying title.
- 11.9 The facility shall also maintain the following:
 - 11.9.1 A log of all patients presenting for treatment performed and entered daily.
 - 11.9.2 Statistical information concerning all admissions, discharges, deaths and other information such as blood usage, treatment complications, etc. required for the effective administration of the facility.
 - 11.9.3 Master patient index file.

12.0 Medications

- 12.1 Medication must be purchased, stored, administered and dispensed in compliance with applicable State and Federal Statutes and Regulations. Those requirements include, but are not limited to the following:
- 12.2 The site must be properly registered under the *State and Federal Controlled Substances Acts*. Any time a change in policy is made it should be dated.
- 12.3 A policy and procedure manual must be established and approved by the Governing Board.

- 12.3.1 It shall be reviewed annually.
- 12.3.2 Any additions or deletions should show an effective date.
- 12.3.3 It shall contain automatic stop orders, labeling requirements, discontinued medication policy, drug storage policy, charting policy, medication error policy, drug recall policy, prescriber medication order procedure, out dated medication procedures.
- 12.4 Standing orders shall be written and administered in compliance with the regulation of the Board of Medical Practice.
- 12.5 Verbal orders must be countersigned by the prescriber within 72 hours of receipt.
- 12.6 Rubber stamp signatures are not acceptable for controlled substances orders.
- 12.7 All records concerning controlled substances must be retained for a period of two (2) years from the last entry. It must show the date of administration or dispensing, the time, the name, strength and quantity of the drug involved, the name of the patient and the initials of the person removing the medication. The same information concerning the receipt of medication must be documented.
- 12.8 Medications shall be properly secured in locked areas only accessible to authorized persons.
 - 12.8.1 Schedule II medications shall be under double lock.
- 12.9 Medication must be stored according to the latest USP/NF standards.
 - 12.9.1 Room temperature 59 to 86 degrees Fahrenheit; refrigerator 36 to 46 degrees Fahrenheit.
- 12.10 Internal medications shall be stored separately from external medications.
- 12.11 All medications shall be accurately and plainly labeled:
 - 12.11.1 Dispensed medications shall be labeled in compliance with 24 **Del.C.** §2563.
 - 12.11.2 Prepacks must be labeled in compliance with Board of Pharmacy Regulation
- 12.13 All medications on site or dispensed must be in packaging which complies with the latest edition of USP/NF.
- 12.14 Medication discontinued must be properly documented on the patient's chart or other applicable record.
 - 12.14.1 Controlled substance documentation should contain two signatures.
- 12.15 Only a physician or pharmacist may dispense medications.
 - 12.15.1 Nurses may assist the physician with dispensing provided the physician directly supervises that person (24 **Del. C.** §2521).
- 12.16 Only licensed nurses and physicians may administer medications.
- 12.17 Stock supplies of controlled drugs can only be destroyed via procedures established by ONDD or DEA.
- 12.18 Syringes must be stored and destroyed in compliance with 16 **Del. C.** §4757, State CSA Regulation 5.

13.0 Infection Control

- 13.1 Prevention and Control Services
 - 13.1.1 The facility shall establish and implement an infection control program. The chief executive officer shall ensure the development and implementation of the program.
 - 13.1.2 The facility shall establish and implement written policies and procedures regarding infection prevention and control, for patients and employees including, but not limited to the following:
 - 13.1.2.1 A system for investigating, reporting and evaluating the occurrence of all infections or diseases which are reportable or conditions which may be related to activities and procedures of the facility and maintaining records for all patients or personnel having these infections, diseases or conditions.
 - 13.1.2.2 Reportable diseases shall be reported to the Director of the Division of Public Health.
 - 13.1.2.3 Care of patients with communicable diseases.
 - 13.1.2.4 Policies and procedures for exclusion from work and authorization to return to work for personnel with communicable diseases.

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- 13.1.2.5 Surveillance techniques to minimize sources and transmission of infection.
- 13.1.2.6 Sterilization, disinfection and cleaning practices and techniques used in the facility including, but not limited to the following:
 - 13.1.2.6.1 Care of utensils, instruments, solutions, dressings, articles and surfaces.
 - 13.1.2.6.2 Selection, storage, use and disposition of disposable and non-disposable patient care items. Disposable items shall not be reused; dialyzer may be reused by facilities providing chronic dialysis services.
 - 13.1.2.6.3 Methods to ensure that sterilized materials are packaged and labeled to maintain sterility and to permit identification of expiration dates.
 - 13.1.2.6.4 Procedures for care of equipment and other devices that provide a portal of entry for pathogenic micro-organisms.
 - 13.1.2.6.5 Techniques to be used during each patient contact, including handwashing before and after caring for a patient.
 - 13.1.2.6.6 Criteria and procedures for isolation of patients.
- 13.1.2.7 Each service in the facility shall develop written infection control policies and procedures for that service.
- 13.1.2.8 All personnel shall receive orientation at the time of employment and continuing inservice education regarding the infection prevention and control program.
- 13.2 Infectious Disease and Waste Removal
 - 13.2.1 The facility shall establish and implement policies and procedures for the collection, storage, handling and disposition of all pathological and infectious wastes within the facility, and for the collection, storage, handling and disposition of all pathological and infectious wastes to be removed from the facility, including, but not limited to the following:
 - 13.2.1.1 Needles and syringes shall be destroyed or disposed of in a safe and proper manner.
 - 13.2.1.2 Needles and syringes and other solid, sharp or rigid items shall be placed in a puncture resistive container and incinerated or compacted prior to disposal.
 - 13.2.1.3 Non-rigid items, such as blood tubing and disposable equipment and supplies, shall be incinerated or placed in double, heavy duty, impervious plastic bags and disposed.
 - 13.2.1.4 Fecal matter and liquid waste, such as blood and blood products, shall be flushed into the sewerage system.
 - 13.2.1.5 All pathology specimens and waste, including gross and microscopic tissue removed surgically or by any other procedure, shall be incinerated.
 - 13.2.1.6 Solid waste from the laboratory shall be incinerated or autoclave prior to disposal.
 - 13.2.1.7 Liquid waste from the laboratory shall be autoclave prior to disposal into the sewerage system.
- 14.0 Equipment and Supplies
 - 14.1 There shall be appropriate equipment and supplies maintained for the Free Standing Emergency Center to include, but not limited to:
 - 14.1.1 Immediately available oxygen with flow meters and masks or equivalent.
 - 14.1.2 Immediately available mechanical suction.
 - 14.1.3 Airway maintenance and resuscitation equipment to include resuscitation bags, laryngoscopies and blades of varying sizes and shapes, endotracheal tubes, cricothyrotomy tubes and adapters. Ventilation devices must be capable of delivering 1000 oxygen.
 - 14.1.4 Spine immobilization equipment to include sandbags and/or semi-rigid collars.
 - 14.1.5 Complete intravenous infusion sets and standards with a reserved supply of at least six liters PSS or RL.
 - 14.1.6 Cardiac monitors and defibrillators together with an effective cardiac pacing system.
 - 14.1.7 Equipment and supplies needed to empty and drain stomachs and bladders.

14.1.8 Newborn and pediatric resuscitation equipment.

14.1.9 Sterile suturing equipment and supplies.

15.0 Plant, Equipment & Physical Environment

15.1 Site Provisions:

15.1.1 Each institution shall be located on a site which is considered suitable by the Division of Public Health. Site must be easily drained, must be suitable for disposal of sewage and furnishing a potable water supply.

15.2 Water Supply and Sewage Disposal:

15.2.1 The water supply and the sewage disposal system shall be approved by the Division of Public Health and the Department of Natural Resources and Environmental Control respectively.

15.2.2 The water system shall be designed to supply adequate hot and cold water, under pressure, at all times.

15.3 Building:

15.3.1 All new construction, extensive remodeling or conversions shall comply with the standards set forth under the "Free Standing Emergency Facility" section of the current or subsequent editions of "General Standards of Construction and Equipment for Hospitals and Medical Facilities", a publication of the U.S. Department of Health and Human Services.

15.3.2 Each facility shall provide the following:

15.3.2.1 Entrance and driveway shall be clearly marked. If platform is provided for ambulance use, a ramp for pedestrian and wheelchair access must be provided.

15.3.2.2 Reception and control station shall be located to permit staff observation and control of access to treatment area, pedestrian and ambulance entrances and public waiting area.

15.3.2.3 Wheelchair and stretcher storage shall be provided for arriving patients. This shall be out of traffic with convenient access from emergency entrances.

15.3.2.4 Public waiting area with toilet facilities, drinking fountains and telephones shall be provided.

15.3.2.5 Each treatment /examination room(s) shall have at least 7.43 square meters (80 square feet) of clear floor space and shall contain work counter(s), cabinets, hand wash facilities and have access to x-ray film illuminators and examination lights.

15.3.2.6 If the facility provides trauma services, trauma room(s) for emergency trauma procedure, including emergency surgery shall have at least 13.37 square meters (144 square feet) of clear floor space. Each room shall have cabinets and emergency supply shelves, and have access to x-ray film illuminators, and examination lights. Additional space with cubicle curtains for privacy may be provided to accommodate more than one patient at a time in the trauma room.

15.3.2.7 Orthopedic and cast work may be in separate room(s) or in the trauma room. They shall include storage for splints and other orthopedic supplies, a plaster sink and have access to x-ray film illuminators and examination lights.

15.3.2.8 Adequate hand washing facilities convenient to each treatment area shall be provided.

15.3.2.9 Convenient on-site access to radiology and laboratory service.

15.3.2.10 Provide for poison control with immediate access to antidotes and file of common poisons as well as provisions for communication with regional and/or national poison centers. This may be part of the nurses' control and work station.

15.3.2.11 Provisions for disposal of solid and liquid waste. This may be a clinical sink with bedpan flushing device within the soiled workroom.

15.3.2.12 Storage area for "crash cart", and other equipment located out of traffic and easily accessible to each trauma and treatment room.

15.3.2.13 Toilet room for patients and staff.

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- 15.3.2.14 Storage rooms for clean and soiled or used supplies. Soiled and clean rooms shall be separated without direct connection.
- 15.3.2.15 Staff work and charting area station with counters, cabinets and medication storage. This area may be combined with, or include, centers for reception control, poison control and communication. Provide for convenient access to handwashing facilities.
- 15.4 Plumbing
 - 15.4.1 The plumbing shall meet the requirements of all municipal, country or state codes. Where there are no local codes, the provisions of the Division of Public Health regulations governing a detailed plumbing code shall prevail.
- 15.5 Heating/Air Conditioning
 - 15.5.1 The heating and air conditioning equipment for all sections of the building shall be adequate, safe, protected and easily controlled. It shall be capable of maintaining the temperature in each room at a minimum of 72 degrees F. (21 degrees C) and not to exceed 81 degrees F. Portable heating equipment is strictly prohibited.
- 15.6 Lighting:
 - 15.6.1 Each room must be suitably lighted at all times for maximum safety, comfort, sanitation and efficiency of operation. This includes hallways, stairways, storerooms and bathrooms.
 - 15.6.2 An alternate emergency power source to sustain lighting must be provided.
- 15.7 Electrical:
 - 15.7.1 All electrical requirements shall be in compliance with all municipal or county codes.
- 15.8 Mechanical Equipment
 - 15.8.1 Mechanical equipment shall be kept in working order at all times.
- 15.9 Pest Control
 - 15.9.1 The building shall be so constructed and maintained to prevent the entrance or existence of rodents and insects at all times.
- 15.10 Sanitation and Housekeeping.
 - 15.10.1 A secured ventilated janitor's closet shall be provided for each floor. This closet will contain a service floor/level sink, hot and cold water and mixing faucet.
 - 15.10.2 Linen Services:
 - 15.10.2.1 On Site Processing Requirements: The laundry shall include: One room with separate areas for receiving, sorting and washing of soiled linen; one room for drying, mending and storing of clean linen; and handwashing facilities immediately accessible to both the preceding areas.
 - 15.10.2.2 Off Site Processing Requirements: Laundry that is sent out shall be sent to a commercial or hospital laundry. A contract for laundry services performed by commercial laundries shall meet all local and state regulations.
 - 15.10.2.2.1 If soiled linen is not processed on a daily basis, a separate, properly ventilated storage area shall be provided.
 - 15.10.2.2.2 The linens to be returned from the outside laundry to the facility shall be completely wrapped or covered to protect against contamination.
 - 15.10.2.2.3 Clean Linen Storage Area: Adequate provisions shall be made for storage of clean linen.
 - 15.10.2.3 There shall be a reasonable amount of clean linen available at all times.
 - 15.10.3 All rooms and every part of the building shall be kept clean, safe, orderly and free of offensive odors.

16.0 Fire Safety

- 16.1 Fire Safety in a Free Standing Emergency Center shall comply with the adopted rules and regulations of the State Fire Prevention Commission. Enforcement of the State Fire Regulations is the responsibility of the State Fire Prevention Commission. All applications for license or renewal of license must include, with the application, a letter certifying compliance

by the Fire Marshal having jurisdiction. Notification of non-compliance with the Rules and Regulations of the State Fire Prevention Commission shall be grounds for revocation of license.

16.2 Accident Prevention:

16.2.1 There shall be a written evacuation and fire plan for the removal of patients in case of fire and other emergencies. The plan shall be posted in a conspicuous place in the building.

16.2.2 A simulated drill shall be performed every quarter per work shift. A written record of each drill shall be kept on file.

17.0 Severability

17.1 Should any section, sentence, clause or phrase of these regulations be legally declared unconstitutional or invalid for any reason, the remainder of said regulations shall not be thereby affected.